4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-D-1253]

Laser-Assisted In Situ Keratomileusis Lasers--Patient Labeling Recommendations; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "Laser-Assisted In Situ Keratomileusis (LASIK) Lasers--Patient Labeling Recommendations." This draft guidance recommends content and formatting for patient labeling information for LASIK devices. FDA is issuing this guidance to help ensure that physicians can share and patients can understand information on the benefits and risks of these devices. The recommendations are being made based on concerns that some patients are not receiving and/or understanding information regarding the benefits and risks of LASIK devices. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your

comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2022-D-1253 for "Laser-Assisted In Situ Keratomileusis (LASIK) Lasers--Patient Labeling Recommendations." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper

submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Laser-Assisted In Situ Keratomileusis (LASIK) Lasers--Patient Labeling Recommendations" to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD

20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Bradley Cunningham, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1414, Silver Spring, MD 20993-0002, 301-796-6484.

SUPPLEMENTARY INFORMATION:

I. Background

LASIK is currently one of the most commonly performed elective procedures in the world, as well as the most popular form of refractive surgery that patients choose to correct common vision problems such as nearsightedness, farsightedness, and astigmatism.[1] On April 25, 2008, FDA convened its Ophthalmic Devices Panel of the Medical Devices Advisory Committee to discuss recommendations for modifications to patient labeling of excimer lasers for LASIK as well as other LASIK-related activities. Since the LASIK Advisory Committee meeting, FDA has continued to gather new information pertaining to risks associated with LASIK. This draft guidance recommends content and formatting for patient labeling information for LASIK devices. FDA is issuing this guidance to help ensure that physicians can share and patients can understand information on the benefits and risks of these devices. The recommendations are being made based on concerns the Agency has received regarding patients not receiving and/or understanding key information regarding the benefits and risks of LASIK devices. These labeling recommendations are intended to enhance, but not replace, the physician-patient discussion of the benefits and risks of LASIK devices that uniquely pertain to individual patients.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current

[1] Vitale S., Cotch M.F., Sperduto R., and Ellwein, L., et al. "Costs of Refractive Correction of Distance Vision Impairment in the United States, 1999-2002," *Ophthalmology*, vol. 113, pp. 2163-2170, 2006.

thinking of FDA on "Laser-Assisted In Situ Keratomileusis (LASIK) Lasers--Patient Labeling Recommendations." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products. This guidance document is also available at https://www.regulations.gov or https://www.fda.gov/regulatory-information/search-fda-guidance-documents. Persons unable to download an electronic copy of "Laser-Assisted In Situ Keratomileusis (LASIK) Lasers--Patient Labeling Recommendations" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 16053 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR Part	Topic	OMB Control No.
814, subparts A through E	Premarket approval	0910-0231
800, 801, and 809	Medical Device Labeling Regulations	0910-0485

Dated: July 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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